

## REMARKS

New claims 129-172 now appear in this application for the Examiner's review and consideration. Previously pending claims 85-128 have been cancelled with many of those claims re-written and appearing in the current claim set. In particular, new applicator claims 129-136 and new method claims 157-162 are newly added. Dependent claims 137-156 are renumbered versions of previous claims 93-101, 105-113, and 115-116, all ultimately depending upon claim 129, while dependent claims 163-172 are renumbered versions of previous claims 118-125 and 127-128, all ultimately depending upon claim 157.

The specification has been amended at paragraphs [0022], [0052 to [0054] and [0146] primarily to conform the introductory portion of the specification in the section titled "Summary of the Invention" to the language now used in the claims. In addition, the description of Fig. 10, as appearing on page 37 of the specification (published paragraph [00146]), has also been revised to provide clear antecedent terminology for the language used in the claims. It is believed that all the amendments made to the specification, particularly with respect to Fig. 10, are clearly supported by the original specification and drawings and therefore do not involve any question of "new matter". For example, the original specification referred to the "conical silicon structure 114" (page 37, line 13) provided "to ensure flexibility and effective sealing" (page 37, lines 6-7). Silicon is clearly an elastomeric plastic material, and therefore the amended terminology does not introduce any question of "new matter". Thus, the specification amendments should be entered at this time.

Applicant appreciates the indication of allowable subject matter in previous claims 109-113, 115, 116 and 121-125, and note that these claims have been renumbered as current claims 150-156 and 166-172. In view of the following comments it is believed that these all claims are now in condition for allowance so that it is not necessary to re-write claims 150-156 and 166-172 in independent form.

Independent applicator claim 85 was rejected over Parsons US Patent 191,775, while certain dependent claims were rejected over Petersen et al. US Patent 5,156,846, Norton et al. US Patent 5,976,556, Gibbons US Patent 5,697,920 and Ignon et al. US Patent 6,942,619. Method claim 117 was rejected over various combinations of the previous claims with the addition of Clague et al. US Patent 5,441,482, and Vaughn US Patent 5,282,392. These references have been carefully studied, and the claims have been revised in order to more clearly

define the invention of the present application, and to more sharply distinguish the invention from these references. No new matter had been added by these amendments so that these changes should be entered at this time to place the entire application in condition for allowance. Favorable reconsideration of the application is respectfully requested in the light of these amendments and the following remarks.

There are two independent claim in this application, claim 129 directed to an applicator and claim 157 directed to a method of use. Claim 157 is specifically directed to the method of treating a skin portion of a subject inflicted with a dermatological lesion comprising: producing a stream of a solution containing an effective amount of at least protease; and directing the solution in the form of a stream into and out of contact with the skin portion such that the protease solution stream enzymatically and mechanically removes cells from the skin portion.

It will thus be seen that the method of Claim 157 involves removal of the cells from the skin by two actions: (1) an enzymatical removal action, produced by the protease (an enzyme) brought into contact with the skin; and (2) a mechanical removal action, produced by streaming the solution into and out of contact with the skin. It is not seen that any of the cited references discloses such a double-action removal of cells from the skin.

In particular, the Parsons patent merely discloses a syringe. Syringes have been known for a long time, but the present invention is much more than a simple syringe. This patent may have some similarity to the applicator of the present invention, as will be discussed more particularly below with respect to the applicator claims, but it certainly has no particular relevance to the method that is defined in claim 157. It does not disclose the presently claimed double-action removal technique, involving both an enzymatical removal action produced by the protease enzyme, and a mechanical removal action produced by streaming the solution into and out of contact with the skin. Thus, Parsons is not relevant to the present claims and all rejections of the method claims based on Parsons should be withdrawn.

Petersen et al. relates to a percutaneous drug delivery system for delivering an enzyme solution to an area of the skin "to allow the drug to penetrate through the skin and into the circulatory system" (see the Abstract). The drug delivery system described is in the form of a patch, as illustrated for example in Figs. 12-16. Thus, the purpose of the enzymatic treatment described in that patent is "to enhance the skin's permeability to a selected drug or drugs"

(column 4, lines 30–140). While this patent may or may not have relevance to removing cells by an enzymatical action, it certainly has no relevance to removing cells by a mechanical action, such as produced by the streaming operation of a protease solution as defined in claim 157.

Norton et al. discloses a number of protease compositions, but these are described for topical application to treat dry skin, dandruff, acne, etc. This patent, therefore, also has no relevance to the mechanical removal of cells from the skin by a streaming action, as defined in claim 157.

Gibbons relates to a brush for cleaning skin and removing contaminants. The removal is effected by soft plastic bristles of a brush. This patent, therefore, has no relevance to either enzymatical removal of cells from the skin, or mechanical removal of the cells by a streaming action, as defined in method claims 157 and 161.

Ignon et al. relates to a system and method for microdermabrasion of the skin. As pointed out by the patentee, microdermabrasion wears away cell layers of the skin, and therefore tends to create a wound on the target skin area (Column 1, lines 23–26). Ignon et al. teaches the provision of a growth factor in the microdermabrasion fluid so as to promote healing of the wounded area. While this patent may have some relevance to mechanical removal of cells by streaming, it has no relevancy to enzymatical removal by including a protease enzyme in the microdermabrasion fluid.

Clearly, therefore, none of the references cited in the last Official Action, discloses, suggests, or renders obvious, the double-action technique defined in method claim 157 for removing cells from skin by streaming a solution into and out of contact with the skin to produce a mechanical removal of cells, and by including a protease enzyme in the stream, to produce also an enzymatical removal of the cells. The growth factor included in Ignon et al. is not for removing cells from the skin, but rather for promoting healing of the skin after cell layers have been removed by microdermabrasion.

Thus, neither Petersen et al., Norton et al., Gibbons nor Ignon et al. remedies the deficiencies of the Parsons patent to render the present method claims unpatentable. It is submitted, therefore, that claim 157 is clearly allowable over the cited references both under 35 U.S.C. 102 and under 35 U.S.C. 103. As new claims 158–172 all depend from claim 157, these are also believed to be allowable with that claim both due to their dependencies as well as for the

additional features that they recite. As noted above, the subject matter of claims 166-172 was already indicated as being allowable in the last Office Action.

New claim 129 is drawn to an applicator for applying a solution containing an effective amount of at least one protease to a skin portion of a subject for treatment thereof. This applicator is particularly suited for performing the method of claim 157 and is also believed to be allowable for the same reasons. It certainly is not anticipated due to the new recitations and the comments submitted above regarding the differences of the invention compared to the cited references.

Parsons does not anticipate new claim 129. In particular, Parsons' syringe does not include a protease solution (i.e., a solution containing an effective amount of at least one protease) to be inletted via the inlet and to be streamed into and out of contact with the skin portion of the subject for enzymatically and mechanically removing cells therefrom. Thus, the anticipation rejection based on Parsons has been overcome and should be withdrawn.

Furthermore, as to the obviousness rejection, Petersen et al. is not properly combinable with Parsons, since, as noted above, Petersen does not relate to a "streaming" treatment, but rather to a "patch" treatment. Nor is Ignon et al. properly combinable with Parsons since Ignon et al. does not relate to an enzymatical removal action. Nor is Gibbons properly combinable with Parsons under 35 U.S.C. 103, since Gibbons relates to a brush-removal action, rather than to an enzymatical removal action. As set forth above with respect to method claim 157, none of the cited references relates to the double-action removal technique or applicator for carrying out such a treatment, which involves both an enzymatical removal action produced by the protease enzyme, and a mechanical removal action produced by streaming the solution into and out of contact with the skin. It is submitted, therefore, that claim 129 is also allowable over the cited references.

Claim 130 depends from claim 129 and brings out further features distinguishing over Parsons, namely: that the body member is a housing having an open end mounting a head; that the head carries a flexible skirt of plastic material, formed with an annular rim to contact the surface of the object to be treated; and that the head is threadedly mounted on the housing to permit axial adjustment of the distance between the annular rim of the skirt and at least one of the passageways, to accommodate irregularities in the surface of the object to be treated.


Claims 131–140 also depend from claims 129 or 130, and are therefore believed to be allowable with those claims apart from the further features set forth in the respective dependent claims. Such dependent claims, however, add still further features not disclosed or obvious from the cited references. For example, claim 131 adds the features that the flexible skirt is of conical configuration, and that the annular rim is an out-turned rim to enhance its contact with the surface of the object to be treated. These features are also not present in Parsons, or any of the other references cited, and therefore it is submitted that these dependent claims are also allowable. Dependent claims 137-156 are also believed allowable for the same reasons. It is noted that the subject matter of claims 150-156 were previously indicated as allowable.

Pursuant to applicant's continuing duty of disclosure under 37 C.F.R. 1.56, enclosed is a PTO form 1449 which lists nine (9) references for the Examiner's review and consideration. Copies of the three non-US publications are enclosed, but copies of the US patents are not provided as these are readily available to the Examiner. Applicant submits that the present claims are patentable over these references and it is respectfully requested that these references be made of record in this application by the Examiner's completion and return of the PTO Form 1449.

Accordingly, applicants respectfully submit that the present claims are patentable over the cited references and that entire application is in condition for allowance. Should the Examiner not agree that all claims are allowable, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the allowance of this application.

Respectfully submitted,

Date: May 30, 2006

  
Allan A. Fanucci (Reg. No. 30,256)

**WINSTON & STRAWN LLP**  
**CUSTOMER NO. 28765**  
(212) 294-3311

## **AMENDMENTS TO THE DRAWINGS**

Applicant submits herewith a Proposed Replacement Page for the Examiner's review and approval. This is submitted to correct Fig. 10 of the drawings as shown in red ink. This correction is being made to correct the lead line from reference numeral "116". As it is believed that this correction will be approved, a formal drawing Replacement Page for Fig. 10 embodying this correction is also enclosed.

PROPOSED REPLACEMENT PAGE

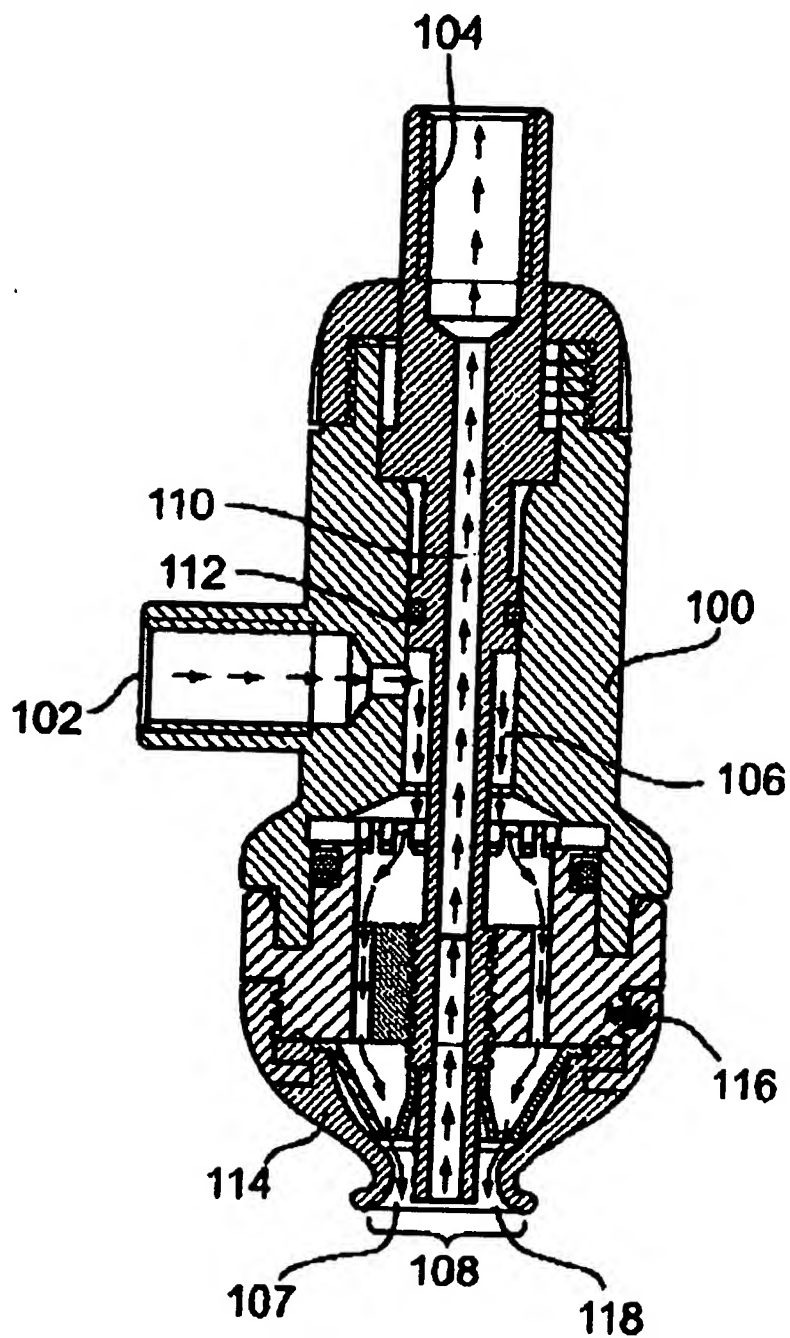


Fig. 10